

### **Remarks**

Claims 35-36, 47-48, 52, 59 and 60 are amended herein. Claim 35 is amended to correct form, namely to remove an abbreviation. Claim 36 is amended to incorporate the limitations of claim 37. Support for the amendment of claims 47-48 can be found throughout the specification, specifically on page 25, lines 32-35, on page 34, lines 3-11, and on page 58, lines 3-35. Support for the amendment of claim 52 can be found in the specification on page 35, lines 22-25. Claim 59 is amended to correct form, in order to properly refer to the subject matter of claim 36. Claim 60 is amended to correct form.

Claim 44 was previously withdrawn from consideration by the Examiner. Claims 44 and 49 are canceled herein.

New claims 69-71 are added herein. New claims 69-70 are added to claim the embodiments set forth in claim 36 individually. Support for new claim 71 can be found in the specification on page 22, lines 10-12.

No new matter is added. Reconsideration of the subject application is respectfully requested.

### **Rejections Under 35 U.S.C. § 101**

Claims 47 and 48 are rejected as allegedly being directed to primates naturally infected with a virus. Applicants note that § 101 states that any new and useful process, machine, manufacture or composition of matter is patentable. The Office action appears to assert that as Searles (published after the priority date of the present application), teaches that RRV can be naturally isolated from macaques, the virus is not “new.” Applicants respectfully disagree with this assertion. Claims 47 and 48 recite that the non-human primate is purposely infected with the virus. Moreover, claims 47 and 48 recite that this virus is isolated and that the non-human primate is “experimentally housed,” as supported throughout the specification, specifically on page 25, lines 32-35, on page 34, lines 3-11, and on page 58, lines 5-35. Viruses occurring in nature are not isolated when they infect a mammal; mammals that are in their natural environment are not experimentally housed. Thus, Applicants submit that the amendments of the claims overcome the rejection.

Claims 59-62 were rejected as allegedly being directed to non-statutory subject matter. The Office action alleges that in nature, a method is performed that includes administering a treatment that renders the primate immunocompromised, and that the primate is infected with RRV in nature. As both steps of the method allegedly could occur in nature, the Office action contends that the claimed subject matter is non-statutory.

Applicants note that in nature a treatment is not “administered” to render to the animal immunocompromised. Moreover, claim 59 is amended herein to recite that the virus is “isolated.” In nature a virus is clearly not isolated. Thus, Applicants submit that it is clear that the “hand of man” is involved in the claimed method. Reconsideration and withdrawal of the rejection is respectfully requested.

### **Claim Objections**

Claim 35 was objected to for including the acronym, “RRV,” to refer to “rhesus radinovirus.” Claim 35 has been amended to remove “RRV,” thereby removing the objection.

Claim 44 was withdrawn from consideration as being directed to non-elected subject matter. In order to advance prosecution, claim 44 is canceled herein.

### **Rejections Under 35 U.S.C § 112, second paragraph**

Claim 52 was rejected as allegedly the biological activities of RRV are indefinite. Applicants respectfully disagree with this rejection.

However, solely to advance prosecution, claim 52 has been amended to refer to one biological activity of RRV, namely that inoculation of an immunocompromised non-human primate with a viral particle comprising the nucleic acid molecule results in lymphadenopathy in the non-human primate. Applicants submit that the amendment removes the rejection.

### **Rejections Under 35 U.S.C. § 112, first paragraph**

Claims 35-37, 47, 48, 52, and 59-62 were rejected as allegedly not being enabled by the specification. The Office action alleges that the virus deposited as ATCC VR-2601 is required to practice the invention, and asserts that the deposit was made without a promise for availability. Applicants respectfully disagree.

Applicants respectfully disagree with this assertion as applied to claims 36-37, 47, 52, 59-62. Claim 36 is directed to a virus including a nucleic acid sequence set forth as SEQ ID NO: 1, or 95% identical to SEQ ID NO: 1. The complete sequence of RRV is provided (see SEQ ID NO: 1 of the sequence listing), and methods for determining sequence identity to SEQ ID NO: 1 are described (see the specification at page 21, line 12 to page 23, line 6). In addition, sequence variants are disclosed (see the specification at page 24, lines 7 to page 25, line 16, page 52, line 10 to page 56, line 50). Moreover, primers are disclosed for the amplification of a portions of the RRV genome (see the specification at page 37, lines 1-36), and to amplify other naturally occurring variants in addition to the disclosed variants (see the specification at page 55, line 36 to page 56, line 1), providing a means to synthetically produce RRV and RRV variants. Applicants do not deny that the deposit is supportive of claims 36-37, 47, 52, and 59-62. However, given the large amount of information provided in the specification, and the high level of skill of one in the art, Applicants submit that the deposit is not required to enable claims to viruses including a nucleic acid molecule comprising a nucleic acid sequence set forth as SEQ ID NO: 1 or a nucleic acid sequence 95% identical to SEQ ID NO: 1.

Claim 35 refers to the virus as deposited. This deposit was made with the ATCC in accordance with the Budapest Treaty, as stated in the specification (see the specification on page 16, lines 29-32), and as shown on the attached receipt from the ATCC (ATTC Designation VR-2601, deposited on March 12, 1998, Exhibit A). It is the Applicants understanding that deposits made with ATCC in accordance with the Budapest treaty must be made available if a U.S. Patent is issued citing the deposited strain. Applicants note that the deposit receipt of for ATCC VR-2601 (Exhibit A) states "The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain...." The form is signed by Barbara E. Hailey, Administrator of the Patent Depository. Applicants submit that the submission of the ATCC receipt removes any rejection of claim 35 under 35 U.S.C. § 112, first paragraph.

Claims 36, 37, 47-48 and 59-62 are rejected as allegedly the specification does not provide sufficient enablement for variants, including conservative variants, of the SEQ ID NO: 1. Applicants respectfully disagree with this assertion.

Variants are disclosed in the specification on page 24, line 7 to page 25, line 16. Moreover, variants of specific ORFs encoded by SEQ ID NO: 1 are shown in the specification on page 55, line 24 to page 56, line 50. Thus, Applicants were in possession of variants at the time the application was filed, and sufficient teaching was provided in the specification that one of skill in the art could readily identify variants of SEQ ID NO: 1. However, solely to advance prosecution, claim 36 has been amended to remove the term "variants." Applicants submit that this amendment renders the rejection moot.

### **Rejections Under 35 U.S.C. § 102(a)**

Claims 35-37 were rejected as allegedly being anticipated by Searles et al. (*J. Virol.* 73:3040-53, 1999). Applicants respectfully disagree with this rejection.

The present application claims the benefit of two provisional applications, U.S. Application No. 60/107, 507, filed November 6, 1998 and U.S. Application No. 60/109,409, filed November 20, 1998, which disclose the entire sequence of RRV. Moreover, an ATCC patent deposit of the viral nucleic acid was made on March 12, 1998, prior to the filing of either of the two parent provisional applications. Thus, claims 35-37 are entitled to the priority date of the earlier filed provisional application.

Searles et al. is a manuscript describing the inventor's own work, which published in a scientific journal. Searles et al. was published after the parent provisional applications were filed, and was published after the virus was deposited with the ATCC. As such, Searles et al. is not available as prior art. Reconsideration and withdrawal of the rejection is respectfully requested.

### **Rejections Under 35 U.S.C. § 103**

Claim 49 was rejected as allegedly being obvious over Genbank Accession No. AF029302, Genbank Accession No. L24487, Genbank Accession No. AF087411, or Davidson et al. (*J. Gen. Virol.* 67:1759-1816, 1986). Claim 49 is canceled herein, rendering the rejection moot.

### Citation of Prior Art

Applicants thank the Examiner for making Kaleeba et al. (*J. Virol.* 73: 6177-81) of record. The Office action notes that Kaleeba et al. does not teach the sequence of an isolated polynucleotide. The Office action notes that Kaleeba et al. does not render obvious claim 52. As no rejections were made based on Kaleeba et al., it is the Applicants understanding that the pending claims are free of this prior art.

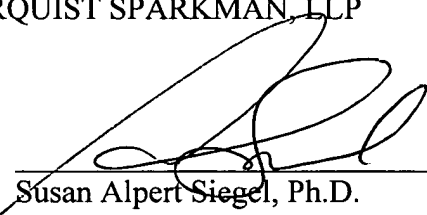
### Conclusion

Applicants believe claims 35-36, 47-48, 52, 59-62, and 69-70 are in condition for allowance, which action is requested. If any matters remain to be addressed before a Notice of Allowance is issued, the Examiner is requested to contact the undersigned for a telephone conference.

Respectfully submitted,

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